

## **The Guideline Development Process**

An Overview for Stakeholders,  
the Public and the NHS

February 2004

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## **The Guideline Development Process – An Overview for Stakeholders, the Public and the NHS**

Issued: February 2004

### **About this document**

This document replaces:

- *The Guideline Development Process – Information for the Public and NHS* (reference N0038)
- *The Guideline Development Process – Information for Stakeholders* (reference N0039)
- *The Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups* (reference N0040)

This document describes the process by which, at the time of issue, NICE guidelines are developed. The document will be updated as described in section 1.1.

Nothing in this document shall restrict any disclosure of information by the Institute that is required by law (including in particular but without limitation the Freedom of Information Act 2000)

The document is available from the NICE website ([www.nice.org.uk](http://www.nice.org.uk)) or from the NHS Response Line (telephone 0870 1555 455 and quote reference number N0472). A related document, *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers*, is also available from the website.

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The Patient Involvement Unit

King's College London

The guidelines team at NICE

The senior management team at NICE

The Institute's Board

The Institute thanks the stakeholder organisations that responded to the consultation for their valuable comments.

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# 1 Introduction

The National Institute for Clinical Excellence (also referred to as ‘the Institute’ or ‘NICE’) was set up as a Special Health Authority for England and Wales on 1 April 1999. It is part of the NHS, and its role is to provide authoritative and reliable guidance on healthcare for patients, healthcare professionals and the wider public.

The Institute produces guidance from a number of its work programmes. Although the methods for developing the various forms of guidance differ, all the development processes are underpinned by the key Institute principles of basing recommendations on the best available evidence and involving all stakeholders (the patients and carers, healthcare professionals, NHS bodies and companies with an interest in the guidance under development) in a transparent and collaborative manner. There is more information on the development processes for each of the Institute’s work programmes on the NICE website ([www.nice.org.uk](http://www.nice.org.uk)).

This document provides an overview of the Institute’s clinical guideline development process. In particular, it describes:

- how organisations can register as stakeholders
- the stages of the guideline development process at which registered stakeholders can contribute
- how stakeholders can contribute.

The Institute has also produced a more detailed resource describing the methods used in the development of its guidelines, titled *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers*. Although this has been produced primarily for the National Collaborating Centres and guideline developers, some information may be of wider interest. It is available as a PDF from the NICE website ([www.nice.org.uk](http://www.nice.org.uk)).

A glossary of terms and a list of abbreviations are provided as Appendix A.

The Institute welcomes comments on the content of this document. These should be emailed to: [Mercia.Page@nice.nhs.uk](mailto:Mercia.Page@nice.nhs.uk)

## 1.1 Updating this document

The formal process for updating this document will begin 3 years after publication. In exceptional circumstances, and only when it is anticipated that there will be significant changes, the interval will be reduced to 2 years.

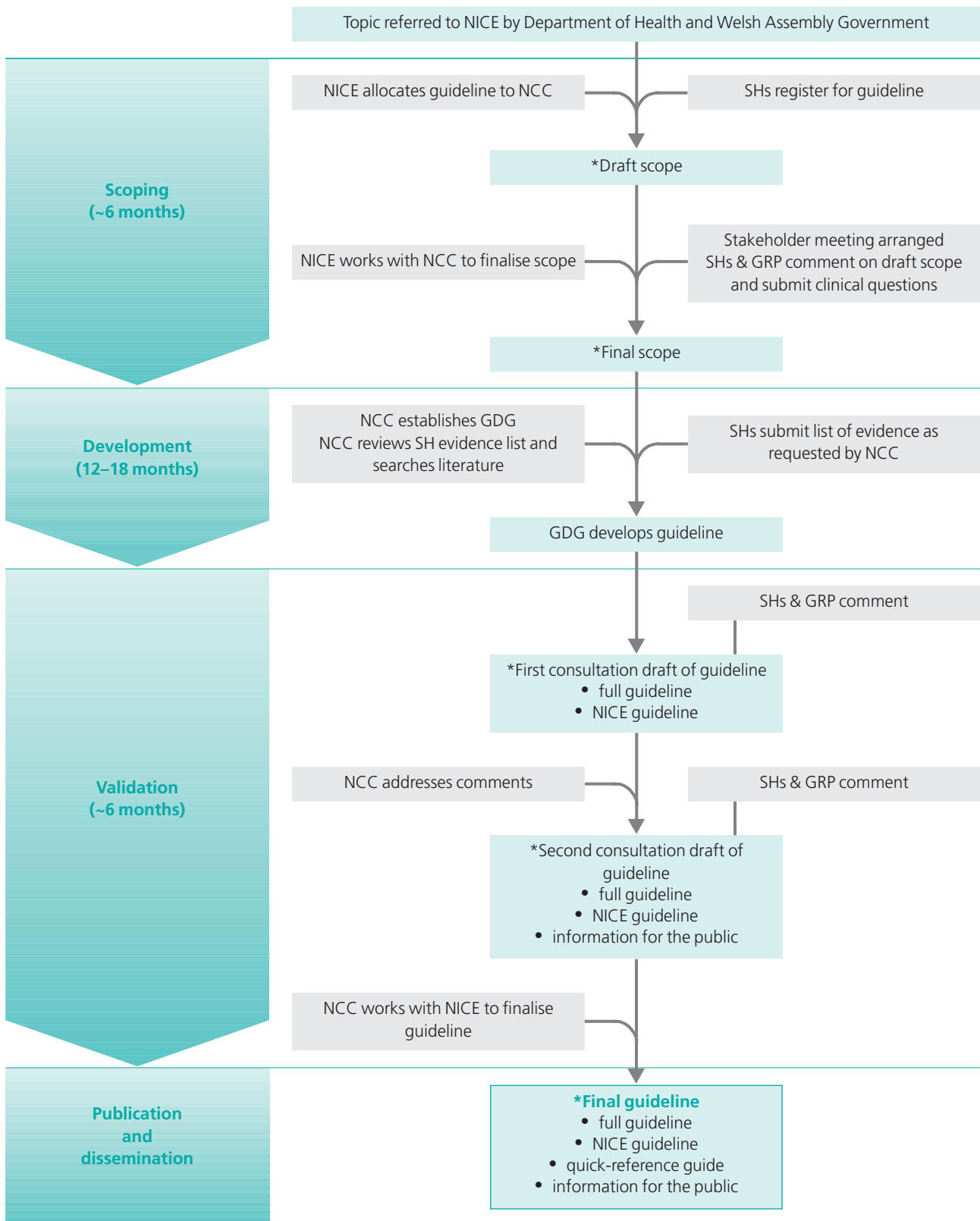
### 1.1.1 Interim updates

In some situations, it may be necessary to make small changes to the process prior to a formal update. These may be either minor, insubstantial changes (‘bug fixes’), or more significant changes where formal consultation with stakeholders will be necessary. For small changes to be put in place without stakeholder consultation, they must fulfil all the following criteria:

- a fundamental stage in the process is neither added nor removed
- a fundamental methods technique or step is neither added nor removed
- one or more stakeholders will not obviously be disadvantaged
- the efficiency, clarity or fairness of the process or methodology will be improved.

Changes that meet these criteria will be published on the Institute’s website, in a special updates section, 4 weeks in advance of their implementation. At the same time, the web version of this document will be updated and a note to this effect placed on the opening page. Stakeholders in guidance under development at the time of change will be notified, if they are affected by the change. Stakeholders in newly commissioned guidance will be advised to consult the website to familiarise themselves with the updated process at the start of the project.

Figure 1 Overview of the guideline development process, showing key activities of the National Collaborating Centre (NCC), stakeholders (SHs), Guideline Development Group (GDG) and Guideline Review Panel (GRP).



\*Posted on the NICE website ([www.nice.org.uk](http://www.nice.org.uk))

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## 2 The Institute's guidance

The Institute issues guidance developed through its clinical guidelines, technology appraisals and interventional procedures work programmes. The Institute's clinical guidelines cover specific aspects of clinical care and the clinical management of specific conditions. In contrast, its technology appraisals cover the use of individual medicines, medical devices, diagnostic techniques, surgical procedures and other clinical interventions. The interventional procedures programme produces guidance on the safety and efficacy of surgical, endoscopic and endovascular procedures and allied techniques, identifying those safe and efficacious enough for routine use.

Topics developed through the Institute's guidelines programme sometimes extend beyond pure clinical practice guidelines to cover aspects of service delivery. The main example is the Institute's service-delivery guidance. Service-delivery guidance is primarily written for service commissioners rather than health professionals, with a focus on the broad configuration and provision of clinical services rather than on details of clinical practice. It addresses only those interventions that are likely to have implications for the configuration of services.

### 2.1 Clinical guidelines in general

Clinical guidelines are recommendations for the care of individuals by healthcare professionals; they are based on the best available evidence. They have been defined as "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances", although they are also important for health service managers and commissioners.\* Guidelines assist the practice of healthcare professionals, but do not replace their knowledge and skills.

Good clinical guidelines can change the process of healthcare and improve outcomes. For example, well-constructed and up-to-date clinical guidelines:

- ▶ provide recommendations for the management of patients by healthcare professionals
- ▶ can be used to develop standards to assess the clinical practice of healthcare professionals (for example, by the professionals themselves, NHS trusts, health authorities or primary care groups)
- ▶ can be used in the education and training of healthcare professionals
- ▶ can help patients to make informed decisions, and improve communication between the patient and healthcare professional.

However, guidelines are necessarily general, and there will be instances when they will not be appropriate, either wholly or in part, for an individual patient. A guideline (and all Institute guidance) represents the view of the Institute, and has been arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. Healthcare professionals should document the reasons for not following a guideline.

### 2.2 Quality in guideline development

There are a number of features that, by general acceptance, good clinical guidelines have in common (Box 2.1). By using accepted quality criteria, guideline developers minimise the biases inherent in guideline production. Guideline recommendations should be based on the best available evidence. Where this is not available, they should incorporate expert judgement.

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\* The definition is from: Committee to Advise the Public Health Service on Clinical Practice Guidelines. Institute of Medicine. Field MJ, Lohr KN, editors (1990) *Clinical Practice Guidelines: Directions for a New Program*. Washington, DC: National Academy Press.

**Box 2.1 Key features of good clinical guidelines.**

These are drawn from the features identified by the Appraisal of Guidelines Research and Evaluation Instrument (AGREE 2001). More information about AGREE can be found on the website [www.agreecollaboration.org](http://www.agreecollaboration.org)

- The purpose and scope of the guideline are clear
- Stakeholders are involved in the process
- The development of guideline recommendations follows a rigorous process
- The guideline is clear and well presented
- The recommendations can be applied in practice
- Conflicts of interest have been recorded by the guideline developers

**2.3 NICE clinical guidelines**

A clinical guideline, and supporting audit advice, for the management of a certain disease or condition in the NHS (England and Wales) is produced in response to a request from the Department of Health and the Welsh Assembly Government (see below). The Institute's guidelines can cover any aspect of management, from prevention and self-care, through primary and secondary care to more specialised services. The key principles underlying the Institute's clinical guidelines are given in Box 2.2.

**Box 2.2 Key principles underlying the Institute's clinical guidelines.**

NICE clinical guidelines:

- aim to improve the quality of clinical care
- assess the clinical and cost effectiveness of treatments or management approaches
- are advisory, but are expected to be taken into account by clinicians when planning care for individual patients
- are developed through a process that takes account of the views of those who might be affected by the guideline (usually including healthcare professionals, patients and their carers, service managers, NHS trusts, the wider public, Government and the healthcare industries)
- are based on the best possible research evidence and expert consensus
- are developed using methods that are sound and transparent and that command the respect of the NHS and NHS stakeholders, including patients
- set out the clinical care that might reasonably be suitable for the majority of patients using the NHS in England and Wales.

**2.3.1 Proposal of guideline topics**

Topics for guideline development are selected by an advisory committee – the Advisory Committee for Topic Selection (ACTS) – made up of representatives from the Department of Health, the Welsh Assembly Government, the NHS, healthcare industries and patient/consumer organisations.

Topics for referral to the ACTS can be identified in a number of ways:

- from 'mapping' exercises carried out in particular clinical areas ('specialties') to identify where there is an urgent need for guidance (specialty mapping can be carried out either as part of the National Service Frameworks process or as a separate process)
- from horizon scanning, where groups monitor new clinical ideas and/or approaches to treatment or care and identify those that might have a significant impact on patient care and the NHS
- by individual patients, patient groups, professionals, professional groups, NHS, industry and other organisations such as the National Patient Safety Agency.

**2.3.2 Selection of topics**

The ACTS selects topics for guideline development from the list of topics proposed. The following questions are considered.

- Would the guidance promote the best possible improvement in patient care given the available resources? In particular, is one or more of the following satisfied?  
Does the proposed guidance:
  - relate to one of the NHS clinical priority areas, or to other Government health-related priorities, such as reducing health inequalities
  - address a condition associated with significant disability, morbidity or mortality in the population as a whole or in particular subgroups
  - relate to one or more interventions that could significantly improve patients' or carers' quality of life and/or reduce avoidable morbidity or premature mortality, if used more extensively or appropriately relative to current standard practice
  - relate to one or more interventions that, if used more extensively, would impact significantly on NHS or other societal resources (financial or other)
  - relate to one or more interventions that could, without detriment to patient care, be used more selectively, thus freeing up resources for use elsewhere in the NHS?
- Will NICE be able to add value by issuing guidance, taking into account the following factors:
  - is the evidence base sufficient to develop robust guidance across most or all of the interventions to be covered by the proposed guidance
  - is there evidence and/or reason to believe that there is or will be inappropriate practice and/or significant variation in clinical practice and/or variation in access to treatment (between geographical groups) in the absence of the guidance?

The Institute's guideline development process does not begin until a formal referral is made by the Secretary of State for Health and the Welsh Assembly Government.

Further information about the process of topic selection and referral to the Institute can be obtained from [www.doh.gov.uk/nice/consultation2002/](http://www.doh.gov.uk/nice/consultation2002/). Anyone who wants to propose a guideline topic can obtain more information about doing so from the website.

### 2.3.3 Production of the scope and guideline

The Institute does not develop its guidelines in house. Once a guideline topic is accepted on to the NICE programme, the Institute commissions one of seven National Collaborating Centres (NCCs) to develop the scope (see page 13) and subsequent guideline on its behalf. The Collaborating Centre convenes a group (the Guideline Development Group) that includes health professionals and patients and carers to produce the guideline, supported by technical staff employed by the Collaborating Centre (see page 8).

### 2.3.4 Publication of the guideline versions

Each guideline is published in four complementary versions (see Box 2.3, overleaf). The NICE guideline represents the Institute's principal advice to the NHS and contains a full set of recommendations, advice on audit and implementation, resource implications and recommendations for future research.

## 2.4 Linking guidelines to the technology appraisals

As the number of guidelines and appraisals increases, there are more topics spanning both work programmes. Identification of appraisal topics relevant to ongoing guidelines normally takes place during the scoping stage. The final recommendations in the guideline and appraisal aim to be complementary and consistent. In some cases, a newly commissioned guideline topic will cover an area where there is a previously published appraisal. A judgement will be made by the Institute in conjunction with the National Collaborating Centre to determine whether a relevant existing technology appraisal might be usefully updated through the guideline development process. There is more information on the relationship between NICE guidelines and technology appraisals in *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers* (see page 1).

**Box 2.3 The four versions of the clinical guideline.****Full guideline**

The full guideline is the published document that contains all the background details and evidence for the guideline. This document is produced by the relevant National Collaborating Centre. Although styles may differ, all include:

- a summary of the recommendations and algorithm
- background and context of the guideline
- aim and scope of the guideline
- introduction
- methods
- guideline recommendations
- full reference details of the literature in the evidence base
- appendices

**NICE guideline (short form)**

This contains all the recommendations given in the full guideline, without the detailed methods or evidence tables. It represents the principal guidance from the Institute to the NHS. It can be freely reproduced for educational and not-for-profit purposes within the NHS

**Quick-reference guide (from 2004)**

The quick-reference guide presents recommendations in a format most useful to the end user. It aims to contain all guideline recommendations, but may be tailored for different audiences

**Information for the public**

This version:

- presents the information in the NICE guideline for readers with little or no medical knowledge
- can be freely reproduced for educational and not-for-profit purposes within the NHS
- can be reproduced in patient/carer organisations' own material, with the permission of the Institute
- is in language appropriate for a lay reader

## 3 Key groups and individuals

The development of the Institute's clinical guidelines involves:

- ▶ the Institute
- ▶ National Collaborating Centres (NCCs)
- ▶ Guideline Development Groups
- ▶ The Patient Involvement Unit
- ▶ Guideline Review Panels
- ▶ stakeholders
- ▶ the Citizens Council.

The roles of these groups and individuals are described in the following sections. A list of the information available on the Institute's website, in relation to the guideline process, can be found in Appendix B.

### 3.1 The Institute

Following the request from the Department of Health and Welsh Assembly Government to produce a guideline on a particular topic, the Institute commissions the co-ordination of the guideline's development by one of the National Collaborating Centres. The guidelines team at the Institute supports and advises the National Collaborating Centre during the process. When the final draft of the guideline is submitted by the National Collaborating Centre, the Institute's Guidance Executive signs off the guideline for the Institute.

The Guidance Executive comprises the Institute's Executive Directors and Programme Directors. The Guidance Executive receives the guidelines on behalf of the Board of the Institute and checks that the Collaborating Centre has developed the guideline in accordance with the terms of the remit from the Secretary of State for Health and the Welsh Assembly Government and with the Institute's scope, process and methods.

The NICE guideline is then issued to the NHS as NICE guidance.

### 3.2 The National Collaborating Centres

Seven professionally led National Collaborating Centres have been established to support the Institute's delivery of national clinical guidelines (Box 3.1). The Collaborating Centres have the capacity, skills and expertise to deliver products that are of a high quality; each Centre:

- ▶ is professionally led, with requisite academic support
- ▶ works closely with members of the Guideline Development Groups
- ▶ is complementary to the others, sharing skills and expertise
- ▶ employs governance arrangements that assure co-operation, wide participation, consultation and clear contractual accountability
- ▶ has areas of particular expertise but can work on any clinical topic.

**Box 3.1** *The seven National Collaborating Centres established by the Institute to develop its clinical practice guidelines.*

- National Collaborating Centre for Acute Care
- National Collaborating Centre for Cancer
- National Collaborating Centre for Chronic Conditions
- National Collaborating Centre for Mental Health
- National Collaborating Centre for Nursing and Supportive Care
- National Collaborating Centre for Primary Care
- National Collaborating Centre for Women and Children's Health

There is more information about the National Collaborating Centres on the NICE website ([www.nice.org.uk/cat.asp?c=15292](http://www.nice.org.uk/cat.asp?c=15292)).

The National Collaborating Centres have staff with or access to the following range of skills and abilities:

- professional networks to support the proposed range of activities
- expertise in engaging with patients and patient groups
- technical skills for guideline development, including those around:
  - project management
  - guideline development
  - the development of audit advice
  - health economics
  - reviewing evidence
  - using formal methods to reach consensus in the absence of other evidence
  - implementation of the guideline.

### 3.2.1 Role of the National Collaborating Centre

For each guideline, the National Collaborating Centre:

- prepares the first draft scope prior to consultation
- prepares a workplan (which sets out proposed Guideline Development Group membership, the work schedule, timescales, costings)
- establishes and works with the Guideline Development Group in developing the guideline
- ensures development processes are rigorous and documented
- prepares the first and second consultation drafts and the final draft of the guideline
- makes changes in response to the two stages of consultation and in response to the Institute's review processes
- publishes the final full guideline
- advises the Institute on issues around publication, dissemination, implementation and update of the guideline.

## 3.3 The Guideline Development Groups

The Institute commissions the National Collaborating Centre to co-ordinate the development of a guideline. To develop a guideline, the National Collaborating Centre establishes a Guideline Development Group, with membership capable of appraising evidence from systematic reviews of the research evidence, examining clinical- and cost-effectiveness issues, integrating clinical understanding and considering the views of patients and carers. Guideline Development Groups should be small enough to work together effectively – they usually have 12–15 members.

### 3.3.1 Membership

All members of a Guideline Development Group need to have:

- an interest in and commitment to guideline development
- time to attend all meetings (commonly 10–15, held at monthly intervals)
- time to do the background reading and comment on the draft items
- good communication and team-working skills.

Guideline Development Groups may vary in membership depending on the topic, but they are always multidisciplinary, comprising technical experts, clinicians/professionals and patients and/or carers. The Guideline Development Group reflects the range of stakeholders or groups whose professional activities or care will be covered by the guideline and includes at least two lay members with experience or knowledge of patient/carer issues. In addition to the Guideline Development Group members, individuals with relevant expertise may be co-opted for discussions.

While the Institute is not represented on the Guideline Development Group, the Guidelines Commissioning Manager – at the discretion of the group – attends occasional meetings as an observer and receives Guideline Development Group papers.

Manufacturers of pharmaceutical products or medical devices are not represented on the Guideline Development Group because of their actual or potential conflict of interest but have input into the guideline development process through the Guideline Review Panels and as stakeholders.

During the development of the guideline, the Guideline Development Group:

- defines clinical questions, incorporating stakeholder questions as appropriate
- identifies, assesses and synthesises evidence
- translates the evidence into broad findings
- uses expert consensus where evidence is poor or lacking
- formulates the recommendations
- reviews the drafts of the guideline.

More information on the role of the Guideline Development Group is given in *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers* (see page 1).

All members of the Guideline Development Group are expected to abide by a Code of Conduct.

Guideline Development Group members are reimbursed for second class travel and subsistence by the Collaborating Centre.

#### 3.4 The Patient Involvement Unit

The Patient Involvement Unit is funded by the Institute. The Unit's main role is to work with the Institute and the National Collaborating Centres to develop and support opportunities for patient and carer involvement in the development of the Institute's guidance (clinical guidelines, technology appraisals and interventional procedures).

The Patient Involvement Unit provides advice to the Institute itself, and to the individual National Collaborating Centres responsible for developing the Institute's clinical guidelines.

##### 3.4.1 Advice and support to the Institute

The Unit works with the Institute to:

- advise the guidelines team on patient/carer issues
- advise the Guideline Review Panels on patient/carer issues
- identify potential patient/carer stakeholders for individual guideline topics
- facilitate interaction between the Institute and patient/carer organisations
- consult with patient/carer stakeholders at defined points in the guideline development process
- review the Institute's guideline development process and products from a patient and/or carer's perspective
- provide advice and support to patient/carer organisations interested in contributing to the Institute's guideline development process.

##### 3.4.2 Advice and support to the National Collaborating Centres

The Unit works with the Centres to:

- advise on methods for involving patients and carers in the work of the National Collaborating Centres and their Guideline Development Groups
- assist with the identification and nomination of potential patient/carer participants in different Centre activities
- provide technical expertise on methods of involving patients and carers in the development of individual guidelines

- meet the learning needs of patients and carers actively engaged in the Centre's activities
  - provide advice and support to patient/carer members of the Guideline Development Group.
- For information on involving patients/carers in Guideline Development Groups, see Kelson (2001) (details in section 5).

### **3.5 The Guideline Review Panels**

Seven independent Guideline Review Panels have been established to advise and assist in the Institute's guidelines work programme. Each Panel has responsibility for the guidelines developed by one National Collaborating Centre. The Panel members provide external validation for the guidelines by overseeing the development process and reviewing the content of the guidelines. Members are expected to have an in-depth knowledge of the development of their allocated guidelines and keep a record of the documents relating to their guidelines. The Guideline Review Panels are supported by the guidelines team at the Institute.

### **3.6 Stakeholders**

Stakeholders play an integral part in the development of the guidelines. More information on stakeholder involvement is given in the next section.

### **3.7 Citizens Council**

The Institute has established a Citizens Council to help in determining its approach – and that of its advisory bodies – to making social-value judgements. Challenging questions are addressed by a 30-strong group of men and women, broadly representative of the English and Welsh populations and drawn from all walks of life, who meet twice a year. After each meeting the Citizens Council produces a report that is considered in public by the Institute's Board. Over time, the Council's views will influence and inform the Institute's position on how value judgements should influence its advice to the NHS.

## 4 Stakeholder involvement in guideline development

This chapter describes the opportunities for professionals, patients, carers and companies to contribute to, and comment on, the guideline at different stages in the process.

In particular, this chapter describes:

- who can register as a stakeholder
- how to register
- how to contribute during the different stages of the guideline development process.

Figure 1 on page 2 gives a summary of the guideline development process and shows the key points of stakeholder involvement. A summary of stakeholder activities during the process is also given in Table 4.1 below. Appendix C is an information sheet that stakeholders receive when they register.

Stakeholder involvement is managed by the Institute in conjunction with the Patient Involvement Unit. The involvement of stakeholders in the different stages of the development process is described in the following sections.

**Table 4.1** A summary of stakeholder involvement in the guideline development process.

Phase of the guideline development process	Stakeholder activity	See page:
Registering	Register for guidelines of interest	11
Scoping phase	Comment on scope	13
	Attend stakeholder meeting	15
	Nominate potential patient/carer and health professional members of the Guideline Development Group	15
	Submit suggestions for clinical questions	15
Development phase	Submit list of evidence	17
	Submit papers as requested	18
	Participate in additional activity if appropriate	18
Validation phase	Comment on first consultation draft	19
	Comment on second consultation draft	20
Publication and dissemination	Disseminate guideline	20

### 4.1 Stakeholder registration

Stakeholder organisations are encouraged to register their interest in a particular guideline as soon as possible after a new topic is published. However, potential stakeholder organisations can register at any time during the development process and can contribute to the remaining stages in the development of the guideline.

#### 4.1.1 How the Institute alerts potential stakeholders

The Institute publicises the new topics for guideline development by:

- issuing a press release
- posting the topics on the Institute's website, with details on how to register as a stakeholder

- contacting stakeholder organisations that have already registered for previous guidelines to alert them to the new work programme
- writing to any relevant appraisal consultees if the guideline is going to include an update of a technology appraisal
- writing to patient/carer and professional organisations that have not already registered but which may have an interest in a topic on the new programme.

Potential stakeholders should register their interest in appropriate topics as early as possible in the development of a guideline.

#### 4.1.2 Organisations that can register as stakeholders

For the purposes of the Institute's clinical guideline development process, stakeholders are:

- the national patient/carer organisations that represent people whose care is described in the guideline (these stakeholders are referred to as 'patient/carer stakeholders')
- the national organisations that represent the healthcare professionals who are directly providing the services described in the guideline (referred to as 'professional stakeholders')
- the companies that manufacture the medicines or devices used in the clinical area covered by the guideline and whose interests may be significantly affected by the guideline (referred to as 'commercial stakeholders')
- a number of providers and commissioners of health services in England and Wales (selected by the Institute, which aims to ensure an appropriate geographical spread and range of organisations)
- statutory organisations including the Department of Health, the Welsh Assembly Government, NHS Quality Improvement Scotland, the Modernisation Agency and the National Patient Safety Agency
- research organisations with a specific interest in the topic.

As the Institute's guidance is produced for the NHS in England and Wales, a 'national' organisation is defined as one that represents England and/or Wales.

#### 4.1.3 Those not considered as stakeholders

For practical reasons, local patient/carer and professional groups cannot register as stakeholders, and nor can individuals. However, they are encouraged to participate via an appropriate registered stakeholder. The registered stakeholders for each guideline are shown on the NICE website.

#### 4.1.4 How to register

To register an interest in a particular topic, potential stakeholders should complete the 'Stakeholder Interest Form – Clinical Guidelines and Service Guidance'. This form can be completed on the NICE website, printed from the website or requested from the Institute.

The form asks potential stakeholders to:

- provide a brief description of their organisation
- indicate who the organisation represents
- describe briefly the contribution the organisation can make to the guideline
- provide contact details of a nominated person who will act as the principal contact on behalf of the organisation.

Completed forms can be emailed to [guidelines@nice.nhs.uk](mailto:guidelines@nice.nhs.uk) or returned to the Institute by fax. Requests and forms should be marked for the attention of 'Guidelines'.

The Institute will confirm that an organisation has been accepted as a stakeholder. If an organisation does not appear to fit the definition of a stakeholder (see section 4.1.2), registration will not be accepted. Individuals are not accepted as stakeholders (see above).

If a potential stakeholder has not received a confirmation within 28 days, they should contact a member of the Institute's guidelines team.

As the Institute cannot guarantee to notify all organisations that may have an interest in the topic, potential stakeholders are strongly encouraged to visit the Institute's website regularly to check the list of guideline topics and register for appropriate guidelines.

#### 4.1.5 Once an organisation has registered as a stakeholder

Stakeholders are encouraged to check regularly the summary sheets of guidelines for which they are registered stakeholders – these are on the NICE website and are updated regularly. The Institute produces a monthly e-newsletter, which gives details of forthcoming guidance, consultations on guidance in progress, and future events. Subscription to the e-newsletter is free of charge and the e-newsletter is also available on the NICE website.

##### Key point

To participate in the early stages of the guideline development process, potential stakeholders are advised to register within 6 weeks of the announcement of a new topic on the Institute's website. However, potential stakeholders can register at any time during the development process and can contribute to the remaining stages in the development of the guideline.

## 4.2 Scoping phase

Although the Department of Health and Welsh Assembly Government provide the Institute with a remit for the guideline, it is necessary to define exactly what the guideline will (and will not) examine, and what the guideline developers will consider. This process is called 'scoping', and the document containing this information is referred to as the 'scope'.

The scope therefore sets the parameters of the guideline and provides a framework within which to conduct the development work. It describes the background epidemiology relevant to the disease or condition and defines the aspects of care the guideline will cover:

- the population to be included or excluded – for example, age groups or people with certain types of disease
- the healthcare setting – for example, primary, secondary or tertiary care
- the interventions and treatments to be included and excluded – for example, diagnostic tests, surgical, medical and psychological treatments and rehabilitation.

The scope of the guideline is drafted by the clinical experts at the National Collaborating Centre, and is based on the remit given to the Institute by the Department of Health and Welsh Assembly Government.

Stakeholders are able to comment on the consultation draft of the scope. These comments and those from the Guideline Review Panel are considered and the scope is redrafted.

Commenting on the draft scope is, then, the first point at which stakeholders can become involved in the guideline development process.

### 4.2.1 Commenting on the draft scope

Registered stakeholders will receive a copy of the draft scope for a 4-week consultation period. Consultation dates are posted on the Institute's website and in the monthly e-update that is sent out by the Institute. It is important that stakeholders continue to check the Institute's website regularly for any updates to the timelines.

Stakeholders are asked to acknowledge receipt, consider the draft scope and submit comments to the Institute using the form provided. When commenting on the scope, it is important to appreciate what the Institute's clinical guidelines can realistically be expected to cover (see Box 4.1).

Some notes on how to comment on consultation items are given in Box 4.2.

**Box 4.1 Considerations for those wishing to comment on the draft scope.**

- NICE guidelines apply to the NHS only; as services outside the NHS are not required to follow them, NICE will not address the independent sector specifically. However, whenever an independent hospital, clinic or care home, social services or the voluntary sector is commissioned to provide NHS-funded care, those establishments or services will be required to adhere to NICE guidelines and decisions.
- Guidelines are generally published within 2 years of commencement of the development process so that information is up to date at publication. The scope must therefore be confined to what can be realistically covered in this timeframe.
- The guideline will, where appropriate, address what medicines to use, but it is assumed that prescribers will use the appropriate summaries of product characteristics\* to inform prescribing decisions for individual patients, and therefore the guidelines will not necessarily contain detailed information on contra-indications and side effects.
- Clinical guidelines can cover any aspect of healthcare, but do not generally address service configurations, skill mix or staffing requirements.

\* The summary of product characteristics for a medicine includes information on uses, presentations, dosages and contraindications, together with some administrative details; it represents the grounds on which that medicine has been licensed. Summaries of product characteristics can be found at [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)

**Box 4.2 A guide to commenting on drafts (scope and guideline).**

On receipt of the draft (scope or guideline), stakeholders should:

- confirm receipt to the Institute as soon as possible, and indicate the organisation's intention to comment
- circulate the draft, if appropriate, making it clear that it is for consultation purposes and asking recipients to respond to the organisation's stakeholder contact (rather than directly to the Institute)
- prepare and return the organisation's response, remembering to:
  - collate the comments into one response from the organisation on the form provided by the Institute (do not edit the draft document that was sent from the Institute)
  - include the name of the organisation in the organisation's response
  - return the response by the closing date for consultation
- send comments electronically to the dedicated email address given in the letter, adding the organisation's name in the subject box. If it is not possible to use email, comments can be submitted on a floppy disk or CD.

Please keep in mind that:

- the Institute will only accept one response from each registered stakeholder organisation – when several responses are received, it may be unclear which represents the view of the organisation. The Institute does not have the resources to acknowledge or respond to comments from individuals within registered stakeholder organisations
- as all comments received will be made public on the website, confidential information should not be sent
- comments should be constructive and worded clearly
- if comments are not received according to these instructions, and/or are not received by the deadline, they will not be considered
- the designated Guidelines Co-ordinator can answer questions on submitting comments (his or her name is on the summary sheet on the NICE website).

**Key point**

Comments on the draft scope should be submitted within 4 weeks (this is the consultation period), using the form provided by the Institute. Stakeholders are notified of the final date for submission of comments.

#### 4.2.2 Suggesting clinical questions for consideration by the Guideline Development Group

Stakeholders may also suggest clinical questions relevant to the guideline (for example: is there evidence that change in lifestyle [for example, diet or exercise] improves outcomes for patients with diabetes?). These will be considered by the Guideline Development Group, although it is not obliged to accept them.

Clinical questions should be submitted during the scope consultation period, at the same time as comments are submitted on the scope.

A good clinical question is clear and focused. It should be formatted in terms of a specific patient problem because this helps identify the clinically relevant evidence. Its exact structure will depend on the question being asked, but it is likely to fall into one of three main areas: intervention, prognosis and diagnosis.

There is more information about submitting clinical questions in *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers* (see page 1).

#### 4.2.3 Attending the stakeholder meeting

The Institute arranges a meeting for all registered stakeholder organisations during the scope consultation period. Key staff from the Institute, the Patient Involvement Unit and the National Collaborating Centre are present at this meeting. The purpose of the meeting is to:

- provide attendees with an overview of the Institute
- provide attendees with an overview of the guideline development process
- describe the opportunities for stakeholders to contribute to guideline development during the various consultation phases (including opportunities to nominate patient/carer members for the Guideline Development Group)
- discuss the scope of the guideline and hear stakeholders' views
- describe the role of the Patient Involvement Unit
- discuss the submission of evidence by stakeholders
- discuss the selection of Guideline Development Group members.

##### 4.2.3.1 What to do before the meeting

Stakeholders will want to consider carefully who to send to the meeting; the most appropriate people are those with a good understanding of the issues relevant to the guideline topic.

Invited organisations should respond to the Institute. Organisations should not send more than two people to the meeting.

#### Key point

The stakeholder meeting takes place during the scope consultation period. It is important to note that expressing views at the stakeholder meeting does not replace the formal consultation process and comments on the scope should be sent to the Institute during the consultation period.

#### 4.2.4 After the scope consultation

The Institute collates the stakeholders' comments into a 'scope consultation table', which also details the National Collaborating Centre's responses and how the comments have been considered.

The scope is then finalised and signed off by the Guideline Review Panel (see page 10). The final version of the scope is posted on the Institute's website, together with the scope consultation table.

#### 4.2.5 Nominating potential patient/carer members for the Guideline Development Group

Before the stakeholder meeting, the Patient Involvement Unit writes to the patient/carer stakeholders detailing how organisations interested in identifying potential patient/carer members of the Guideline Development Group can do this.

It is recommended that, while patients and/or carers do not need any formal qualifications, they should:

- have a broad understanding of the issues facing patients with the condition, rather than basing views only on their own experience
- be familiar with medical and research language (though training and assistance will be available)
- be willing to network with constituencies not represented on the Guideline Development Group.

When considering who to nominate, stakeholder organisations should bear in mind that:

- some people may find details of research findings about their disease upsetting
- people with particular issues about their own care are likely to find meetings stressful and frustrating if the group is unable to devote time to their particular issue.

Ideally, designated organisations nominate two or three individuals for each place in the Development Group. The organisations should send information on the experience of each nominee to the Patient Involvement Unit by the deadline date agreed. The information should take the form of a personal statement that explains what experiences and expertise relevant to the guideline topic the nominee can draw on to make an effective contribution to the group.

#### **4.2.6 Selection of patient/carers members**

The National Collaborating Centre, in discussion with the Institute where necessary, reviews the nominations to select the best combination of people to maximise the range of skills and experience of the Guideline Development Group. In some cases, nominees may be asked to attend an informal interview or other selection procedure before membership is finalised.

#### **4.2.7 Nominating potential professional members for the Guideline Development Group**

Six to eight members of the Guideline Development Group should be health professionals who are either treating patients with the condition directly or managing services. As part of the workplan, the National Collaborating Centre and the Institute agree jointly the professional groups that have the widest contribution to make to the topic.

Professional members should have:

- an interest in and experience of the guideline topic, but this need not be as an 'expert' – the Guideline Development Group needs clinicians who treat patients on a day-to-day basis within the NHS
- an ability to network within their professional group, but not to act as a delegate for that group. Each professional member should be included in the Guideline Development Group on the basis of his or her individual skills and experience.

#### **4.2.8 Selection of professional members**

The National Collaborating Centre may contact the agreed professional organisations, Royal Colleges or specialist societies requesting two or three nominations per place in the group. The professional organisation is asked to send either a CV or a personal statement to the National Collaborating Centre describing the experience of each nominee. Alternatively, National Collaborating Centres may nominate individuals from a relevant professional body directly, where their skills or experience are considered particularly relevant. As with patient/carers nominations, the National Collaborating Centre identifies the best combination of people to maximise the range of skills, and will provide justification for its selection. In some cases, nominees may be asked to attend an informal interview or other selection procedure before membership is finalised.

#### **4.2.9 Commercial stakeholders**

Commercial stakeholders are not asked to nominate potential members for the Guideline Development Group.

### 4.3 Development phase

Once the workplan for the guideline is agreed, the Collaborating Centre will start the development work. The major activity of the stakeholders at this stage concerns the submission of evidence. Stakeholders are first asked to submit a list of evidence. The lists of evidence are reviewed by the National Collaborating Centre, which then asks for evidence that has not already been found by the National Collaborating Centre during literature searching.

#### 4.3.1 Items that may be listed as evidence

Items that may be listed as evidence for consideration by the Guideline Development Group include:

- systematic reviews
- randomised controlled trials
- other guidelines on the same topic
- representative epidemiological studies (observational)
- qualitative studies or surveys that examine the experiences of patients
- healthcare professionals or carers' experiences of treatment or management
- full company trial reports relating to clinical trials where these provide additional evidence over and above data already published in peer-reviewed journals, provided they are made publicly available
- published or unpublished economic models, but commercial 'in confidence' data will not be accepted
- hospital episode statistics, patient episode data Wales, national or regional registers, national or regional audits (if appropriate).

#### Key point

The type of evidence to be listed in a submission for the development of a guideline differs from that used in the development of the technology appraisal guidance. For guidelines, the National Collaborating Centre asks for **references to relevant literature**, not for submissions of views collected by stakeholders to inform the process.

#### 4.3.2 Information not considered to be evidence

Stakeholders are asked **not to submit** the following:

- studies with 'weak' designs when better studies are available
- commercial 'in confidence' material
- promotional literature
- papers, commentaries or editorials that interpret the results of a published study
- representations or experiences of individuals (unless assessed as part of a well-designed published study).

#### Key point

The National Collaborating Centre writes to all the stakeholders for a particular guideline, inviting them to submit evidence. Stakeholders are asked to acknowledge receipt of the invitation as soon as possible and to indicate whether or not they intend to submit evidence. In the first instance, stakeholders should send a 'list of evidence proposed for submission' to the National Collaborating Centre by the deadline date. The information itself should not be submitted at this stage.

#### 4.3.3 Deciding what to list as evidence

The breadth of the Institute's guidelines means that the volume of submissions and the burden of preparation are potentially large. Stakeholders are encouraged to consider the scope of the guideline and the criteria for evidence (see section 4.3.1) to ensure that the listed evidence is directly relevant.

There is no need to list papers that appear in the usual medical databases as these will be identified by the National Collaborating Centre during its searches. Stakeholders are asked to identify information about studies or 'grey' literature that the National Collaborating Centre may have difficulty identifying or finding.

It is not possible to be completely prescriptive about the kind of evidence that may contribute to the guideline process, as the quality of available evidence varies considerably from topic to topic. If a stakeholder is unsure about the suitability of an item, details of the item should be added to the list of evidence. Providing brief details at this stage will help the National Collaborating Centre decide if the information is useful.

There is more information about types and grading of evidence in *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers* (see page 1).

#### 4.3.4 How to present the evidence

Reference details of published clinical literature can be listed if particularly relevant, though it is likely that these would be identified during the National Collaborating Centre's searches.

For each listed item, the stakeholder should include the following information. A template will be available to help with this.

- Reference details (for example, for journal papers: authors, year of publication, title, journal name and volume, page range; for other publications, include the name of the publisher or sponsor).
- A brief summary of the item and its relevance to the guideline – it will help the Collaborating Centre if the description of relevance includes details of the study population, methods and main findings.

The National Collaborating Centre then reviews the submission list and notifies the stakeholder of the evidence it wishes to consider. The Collaborating Centre asks for complete items to be sent by a deadline (evidence may be submitted electronically or by post, at the discretion of the Guideline Development Group). It is not possible to explain why an item has not been accepted as evidence.

#### Key point

Submission of evidence by stakeholders takes place in two stages.

- 1 Stakeholders are asked to submit an initial list of evidence – the National Collaborating Centre advises the stakeholders of the deadline date (usually 4 weeks).
- 2 Following submission of the initial list, stakeholders may be asked to submit more details of the evidence – again the National Collaborating Centre advises stakeholders of the submission deadline (usually 4 weeks).

The National Collaborating Centre identifies the best and most relevant evidence available using recognised and accepted methods of identification (more information is available in *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers*, see page 1). The National Collaborating Centre then writes the first consultation draft of the guideline over a period of 12 to 18 months.

#### 4.3.5 Wider stakeholder input into development

In some instances, the National Collaborating Centre may use additional methods to obtain wider input on particular issues, and involve stakeholder organisations that do not have members on the Guideline Development Group. For example, the Centre may use expert consensus methods, focus groups and so forth.

### 4.4 Validation phase

The National Collaborating Centre takes 12–18 months to produce a draft guideline, which includes draft recommendations formulated by the Guideline Development Group and explana-

tions of how the developers have interpreted the evidence to make those recommendations. The draft guideline then enters what is called the ‘validation phase’.

The validation phase provides two opportunities for stakeholders to comment on the guideline – the first and second consultation periods.

#### 4.4.1 Commenting on the drafts (both consultations)

Stakeholders are asked to acknowledge receipt, consider the draft guideline and submit constructive comments, using the form provided, directly to the Institute via the dedicated email address for the guideline (given in the email notification and also available from the NICE website). When commenting on the guideline, it is important to remember what is specified in the guideline scope as being included and excluded.

Some notes on how to respond are given in Box 4.2 (see page 14).

##### Key point

Stakeholders usually have 4 weeks in each consultation period to comment on the draft guideline. The developer will not normally respond to late submissions. It is important not to send in confidential information as the consultation tables eventually appear on the Institute’s website.

#### 4.4.2 The first consultation period

Registered stakeholders are notified by email when the first consultation draft is posted on the Institute’s website.

##### 4.4.2.1 What to do in the first consultation period

This consultation period presents the main opportunity for stakeholders to comment on the content and presentation of the proposed guideline. Issues that stakeholders may wish to raise with the guideline developers include:

- a general view (either positive or negative) of the quality and content of the guideline
- points or areas that are not covered by the draft guideline, but which appear to fall within the scope
- gaps in the evidence base used by the Guideline Development Group to formulate the recommendations
- potential inconsistencies in the Guideline Development Group’s interpretation of evidence
- disagreement with the Guideline Development Group’s interpretation of evidence
- the practical value of the guideline, audit advice and implementation issues
- wording (for example, stakeholders may feel that the clarity of the recommendations could be improved, that the language could be more patient-centred or that wording might be perceived as excluding patients or groups of patients)
- observations on the resource consequences of the guideline.

Some notes on how to respond are given in Box 4.2 (see page 14).

#### 4.4.3 After the first consultation

The Institute tabulates all of the comments (the table is referred to as the ‘first consultation draft table’). This is then passed to the National Collaborating Centre to consider and make the appropriate changes to the draft guideline (appropriate changes are made to all versions). The Centre’s responses are added to the consultation table.

A second consultation draft of the guideline is then prepared. In its preparation, the guideline developers consider comments on the first consultation by:

- stakeholders and other reviewers
- the Guideline Review Panel (which is also invited to comment during the consultation period)
- the Patient Involvement Unit.

**Key point**

Stakeholders are sent their own comments on the first consultation draft and the developers' responses at the beginning of the second consultation period, for information.

**4.4.4 The second consultation period**

As for the first consultation, registered stakeholders are notified by email when the second consultation draft is posted on the Institute's website.

**4.4.4.1 What to do in the second consultation period**

This consultation period presents:

- an opportunity to review the changes to the first consultation draft
- the final opportunity to comment on the guideline prior to publication.

New issues should not be raised at this stage.

**4.4.5 After the second consultation**

As with the first consultation draft, all comments on the second consultation draft and responses to them from the guideline developers are collated and tabulated (as the 'second consultation draft table').

In response to advice from the Guideline Review Panel, and in consultation with the Guideline Development Group, the different versions of the guideline are finalised, and are then signed off within the Institute.

Unlike the technology appraisal process, there is no appeal stage in the guideline development process. If a stakeholder has comments on the published guideline, these will be addressed at the time of review (see section 4.6).

**4.5 Publication and dissemination phase**

Once the Institute and the Guideline Review Panel have signed off the guideline, the different versions are published and disseminated. Stakeholders are notified when the guideline is published. At this stage, the first and second consultation tables, including the developers' responses, are posted on the Institute's website.

Stakeholders are encouraged to use their networks and influence to encourage implementation of the guideline at both national and local levels.

The Institute is working with the Department of Health and Welsh Assembly Government, together with other stakeholders, to facilitate implementation of the guidelines.

**4.6 Comments after publication**

If a comment after publication highlights an error in the guideline – in either the interpretation or the presentation of the evidence considered by the guideline developers – the Guidelines Programme Director and the guideline developers will consider whether it:

- undermines the conclusions on which the recommendations have been based
- may result in harm to patients
- opens the Institute to criticism that its quality-assurance procedures are seriously compromised.

If one of these criteria is met, the comment will be referred to the Institute's Guidance Executive. The Guidance Executive then decides what action to take. If an error is not accepted, the individual or organisation that made the comment will be notified of the decision. If the Guidance Executive accepts that an error has been made, stakeholders will be notified via the Institute's website. The version of the document carried on the NICE website will be amended. Depending on the nature and significance of the error and the time since publication, stakeholders may also be notified of the error in writing. A section on the NICE website will be dedicated to error notifications.

### 4.7 Review and update

When the Institute publishes a guideline, it gives a date on which the process of reviewing the guidance will begin. Existing registered stakeholders will remain on the Institute's database and will be contacted when the guideline is due to be updated; however, it is important that stakeholders monitor the Institute's website regularly for information about updates.

## References

AGREE (2001) Appraisal of Guidelines Research and Evaluation Instrument. London: Health Care Evaluation Unit at St George's Hospital Medical School. [www.agreecollaboration.org](http://www.agreecollaboration.org)

Committee to Advise the Public Health Service on Clinical Practice Guidelines. Institute of Medicine. Field MJ, Lohr KN, editors (1990) *Clinical Practice Guidelines: Directions for a New Program*. Washington, DC: National Academy Press.

Kelson M (2001) Patient involvement in clinical guideline development – where are we now? *Journal of Clinical Governance* 9:169–74.

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## APPENDIX A Abbreviations and glossary

### Abbreviations

GDG	Guideline Development Group
GRP	Guideline Review Panel
NCC	National Collaborating Centre
NICE	National Institute for Clinical Excellence
SH	Stakeholder

### Glossary

#### **Appraisal of Guidelines, Research and Evaluation (AGREE)**

An international collaboration of researchers and policy makers whose aim is to improve the quality and effectiveness of clinical practice guidelines (<http://www.agreecollaboration.org>). The AGREE instrument, developed by the group, is designed to assess the quality of clinical guidelines.

#### **Algorithm (in guidelines)**

A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.

#### **Audit**

See 'Clinical audit'.

#### **Carer (caregiver)**

Someone other than a health professional who is involved in caring for a person with a medical condition.

#### **Clinical audit**

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

#### **Clinical efficacy**

The extent to which an intervention is active when studied under controlled research conditions.

#### **Clinical effectiveness**

The extent to which an intervention produces an overall health benefit in routine clinical practice.

#### **Clinical question**

In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.

#### **Clinician**

A healthcare professional providing healthcare, for example doctor, nurse, or physiotherapist.

#### **Cohort study**

A retrospective or prospective follow-up study. Groups of individuals to be followed up are defined on the basis of presence or absence of exposure to a suspected risk factor or intervention. A cohort study can be comparative, in which case two or more groups are selected on the basis of differences in their exposure to the agent of interest.

#### **Commercial in confidence**

See 'In confidence material'.

#### **Consensus methods**

Techniques that aim to reach an agreement on a particular issue. Formal consensus methods include Delphi and nominal group techniques, and consensus development conferences. In the development of clinical guidelines, consensus methods may be used where there is a lack of strong research evidence on a particular topic. Expert consensus methods will aim to reach agreement between experts in a particular field.

### **Consultation**

The process that allows stakeholders and individuals to comment on initial versions of NICE guidance and other documents so their views can be taken into account when producing the final version.

### **Cost-effectiveness model**

An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources in order to estimate the costs and health outcomes.

### **Epidemiological study**

The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (for example, infection, diet) and interventions.

### **Evidence**

Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals and/or patients).

### **Expert consensus**

See 'Consensus methods'.

### **Governance**

Clinical governance is a system through which NHS organisations are accountable for continuously improving the quality of their services and safe-guarding high standards of care, by creating an environment in which clinical excellence will flourish.

### **Grading evidence**

A code given to a study or other evidence, indicating the quality and generalisability of the research. The highest grade evidence will usually be obtained from randomised controlled trials.

### **Grey literature**

Reports that are unpublished or have limited distribution, and are not included in the common bibliographic retrieval systems.

### **Health-related quality of life**

A combination of an individual's physical, mental and social well-being; not merely the absence of disease.

### **Hospital episode statistics**

Information on admitted patients are delivered by NHS hospitals in England and used to provide wide-ranging analysis for the UK government and other organisations who have an interest in health and healthcare administration.

### **In confidence material**

Information (for example, the findings of a research project) defined as 'confidential' as its public disclosure could have an impact on the commercial interests of a particular company or the academic interests of a research or professional organisation.

### **NICE Technology Appraisals**

Recommendations on the use of new and existing medicines and other treatments within the NHS in England and Wales, such as: medicines (for example, drugs), medical devices (for example, hearing aids and inhalers), diagnostic techniques (tests used to identify diseases), surgical procedures (for example, repair of hernias), health promotion activities (for example, patient education models for diabetes).

### **Observational study**

Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups; for example, cohort studies and case-control studies.

### **Opportunity cost**

The opportunity cost of investing in a healthcare intervention is the other healthcare programmes that are displaced by its introduction. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.

**Patient episode data Wales**

A patient-based database for inpatient and daycase activity undertaken in NHS Wales. The database also contains data on Welsh residents treated in England.

**Peer review**

A process where research is scrutinised by experts who have not been involved in the design or execution of the studies.

**Qualitative research**

Research concerned with subjective outcomes relating to social, emotional and experiential phenomena in health and social care.

**Quality of life**

See 'Health-related quality of life'.

**Quick Reference Guide (for a guideline or appraisal)**

An abridged version of NICE guidance, which presents the key priorities for implementation and summarises the recommendations for the core clinical audience.

**Randomised controlled trial (RCT)**

A comparative study in which participants are randomly allocated to intervention and control groups and followed up to examine differences in outcomes between the groups.

**Remit**

The brief given by the Department of Health and Welsh Assembly Government at the beginning of the guideline development process. This defines core areas of care that the guideline needs to address.

**Research Ethics Committee**

An independent committee that scrutinises proposals for research to ensure they are ethically acceptable.

**Service delivery guidance**

Recommendations on service delivery primarily aimed at health service commissioners. Service delivery guidance focuses on the broad configuration and provision of clinical services and addresses only those interventions that are likely to have implications for the configuration of services.

**Stakeholder**

Those with an interest in the use of a technology under appraisal or a guideline under development. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups.

**Synthesis of evidence**

A generic term to describe methods used for summarising (comparing and contrasting) evidence into a clinically meaningful conclusion in order to answer a defined clinical question. This can include systematic review (with or without meta-analysis), qualitative and narrative summaries.

**Systematic review**

Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.

## APPENDIX B Information available from the Institute's website

General information and resources on the Institute's website about the Institute's guidelines programme include:

- contact details for the Institute, the Department of Health and the Welsh Assembly Government
- guideline topics
- stakeholder registration form
- information on the Institute's staff involved in the guidelines work programme
- contact details and information on the National Collaborating Centres
- information on the Guideline Review Panels
- more detailed information about the methods used in the development of the Institute's clinical guidelines (also see page 1)

During the development of a guideline, the information shown below becomes available on the website:

- remit from the Department of Health and Welsh Assembly Government
- list of registered stakeholders
- contact details of the National Collaborating Centre commissioned to co-ordinate development
- key dates
- consultation draft of the scope and final scope
- scope consultation table
- project milestones
- information on the progress of guideline development
- first consultation draft, second consultation draft and final guideline
- first and second consultation draft tables
- Guideline Development Group membership
- details of linked technology appraisals.

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## APPENDIX C The role of a stakeholder in the NICE guidelines process

### Criteria for becoming a registered stakeholder in the NICE guidelines process

As a registered stakeholder, an organisation will have fulfilled the necessary criteria, and will fall into one of the following categories.

- National organisations that represent those patients and carers whose care is described in the guideline.
- National organisations that represent health professionals directly providing those services.
- Manufacturers with technologies in the clinical area covered in the scope of the guideline whose interests are likely to be significantly affected by the guideline.
- Research organisations that have a specific interest in the topic and have nationally recognised research in the area.
- A provider or commissioner of health services in England and Wales (selected by the Institute).
- A Statutory organisation, for example, the Department of Health, the Welsh Assembly Government, NHS Quality Improvement Scotland, the Modernisation Agency or the National Patient Safety Agency.

### Communication with NICE

As a registered stakeholder **one main contact** should be identified who will be the only person to receive information and documents relating to the guidelines/guidance topics for which the organisation has registered. The main contact may therefore feel it necessary to liaise with other members of their organisation, if they have an interest in the same topic, as they will be unable to register for the same topics independently.

All further registrations for new topics should be registered by the main contact.

The main contact should ensure that only one set of comments is sent to NICE following a consultation period. Multiple comments should be collated by the main contact.

Comments submitted jointly by groups of multiple organisations will not be accepted.

**Organisations are asked meet the topic deadlines.** The Institute and the National Collaborating Centres work to tight schedules from start to finish on all topics in order that publication can take place while the information is still in date.

All comments should be collated and forwarded to the Institute on the appropriate form, which is circulated at the beginning of the consultation period.

### Involvement of registered stakeholders

The time that an organisation registers as a stakeholder determines at which stage the organisation will become involved in the process.

- If an organisation registers when a new wave of topics is announced or before the topic scoping period begins, the organisation should expect to be involved with the scope, first consultation and second consultation for the guideline.
- If an organisation registers after the scoping period, it will not be asked to comment on consultation documents until after the development stage, which is approximately 12–18 months long. It will, however, be given the opportunity to submit evidence.

- If an organisation registers after the second consultation period, it will not be involved until the update of the topic, which will be approximately 4 years later.

### Scoping period

- The main contact will receive an email prior to the consultation period notifying him or her when the consultation period will start.
- On the day the consultation begins, the main contact will receive an email containing the draft scope document, plus the table that the organisation is required to use to submit comments.
- When comments are submitted to the appropriate email address, an automatic response will be sent to acknowledge receipt of the comments. If a response is not received, the sender should contact the Guidelines Coordinator responsible for the project to ensure that the comments were received.
- The main contact will receive a reminder of the end of the consultation.

### First/second consultation

- The main contact will receive an email notifying him or her when the consultation period will start.
- On the day the consultation begins, the main contact will receive a link to the NICE website where the relevant documents are posted, plus the table that the organisation is required to use to submit comments. Please note that some consultation documents are large.
- When comments are submitted to the appropriate email address, an automatic response will be sent to acknowledge receipt of the comments. If the sender does not receive this response, he or she should contact the Guidelines Coordinator responsible for the project to ensure that the comments were received.
- The main contact will receive a reminder of the end of the consultation.

### Changing contacts or ceasing stakeholder involvement

If the organisation's contact details change, please notify the Institute, as it will assist with the administration of the consultation periods and will allow the organisation the maximum amount of time to participate.

If the details of the main contact change, please notify the Institute by email, stating the changes (for example, the name and email address of a new contact).

If the organisation no longer wishes to participate in the process, please notify the Institute by email.

### Keeping up to date with guideline topics

Although reminders of consultation periods and so forth are emailed by the Institute, stakeholders can keep up to date with project progress by looking at the 'Clinical Guidelines in progress' section of the NICE website ([www.nice.org.uk](http://www.nice.org.uk)).









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